

TOP SECRET

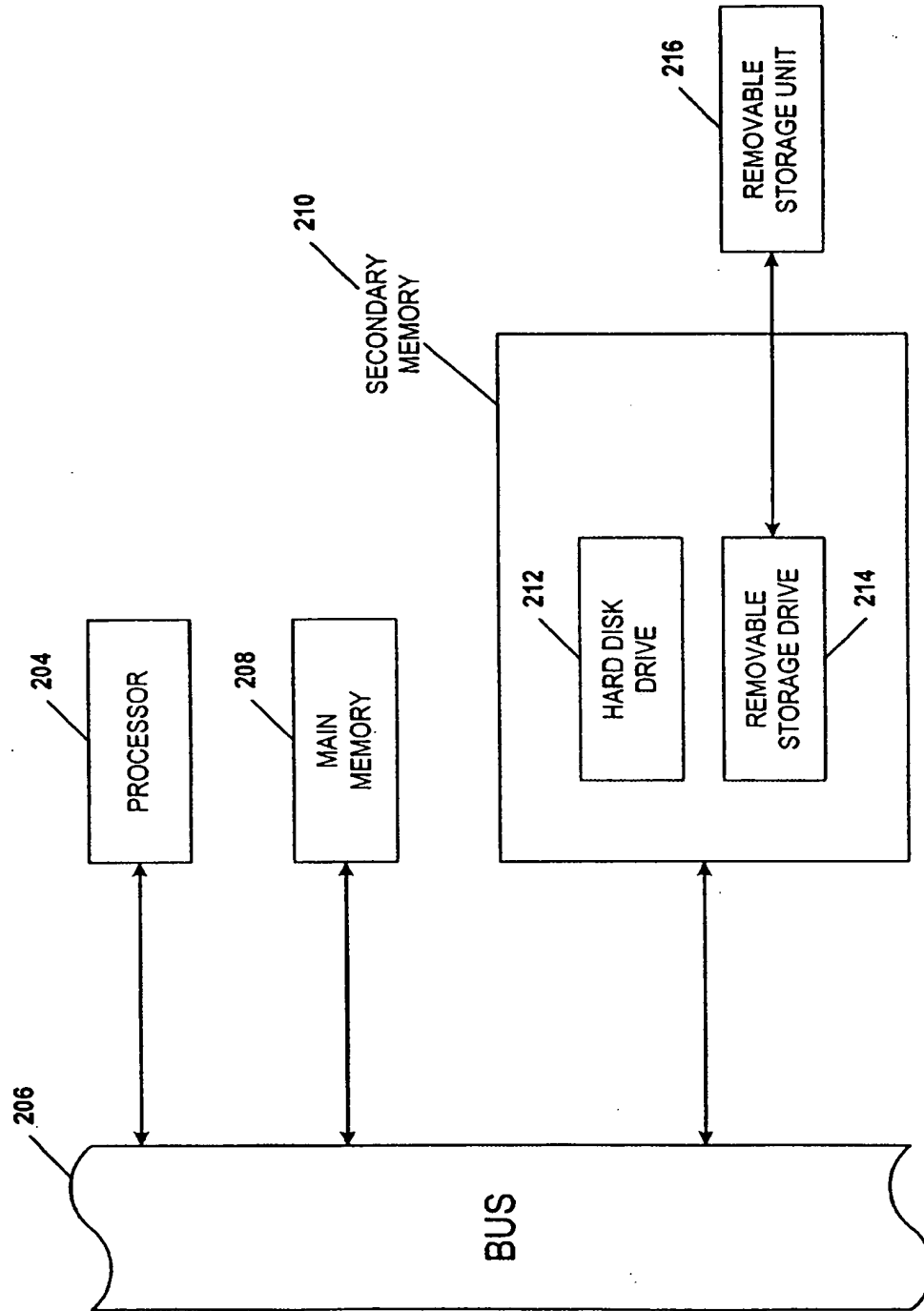


Figure 1

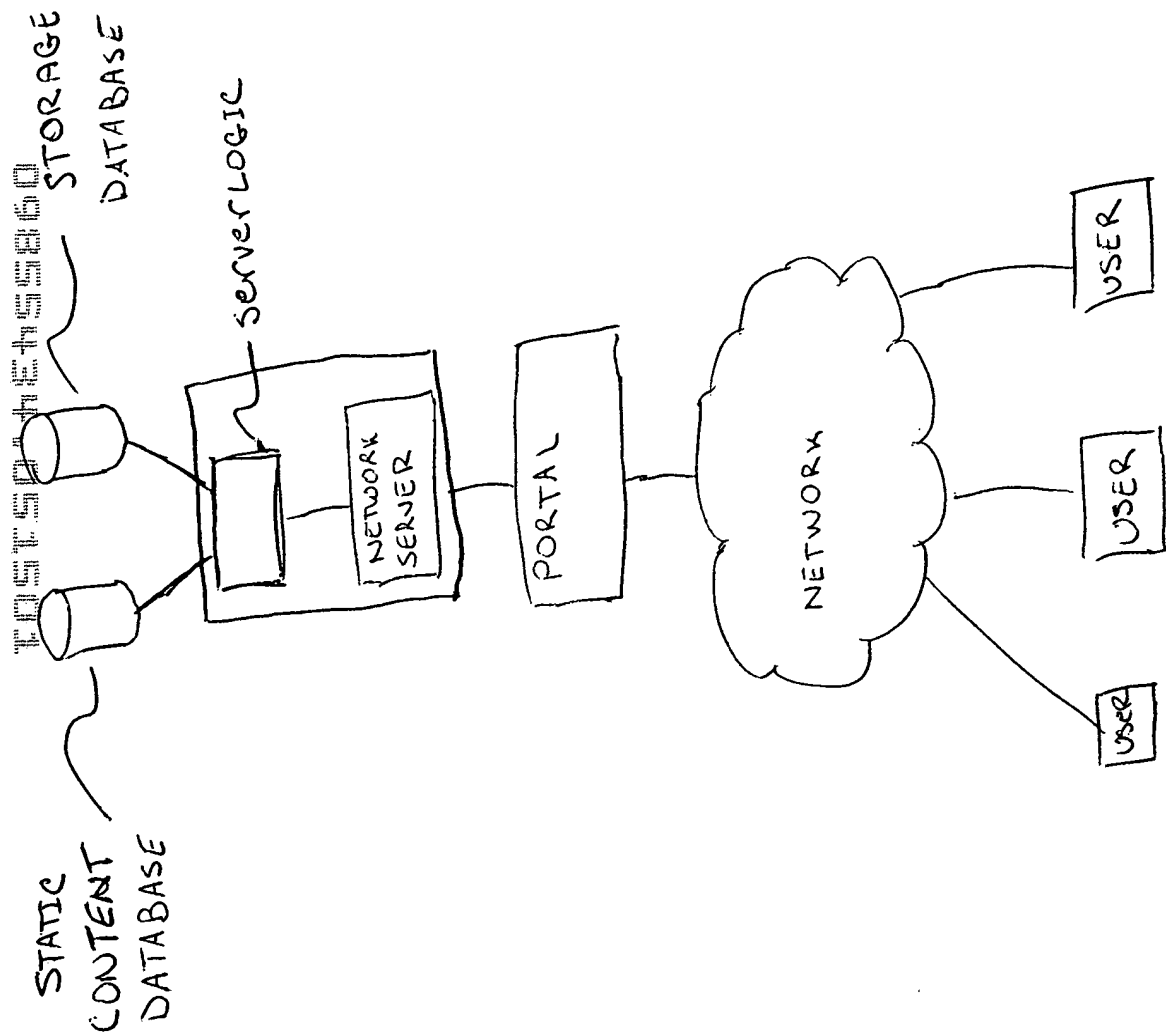
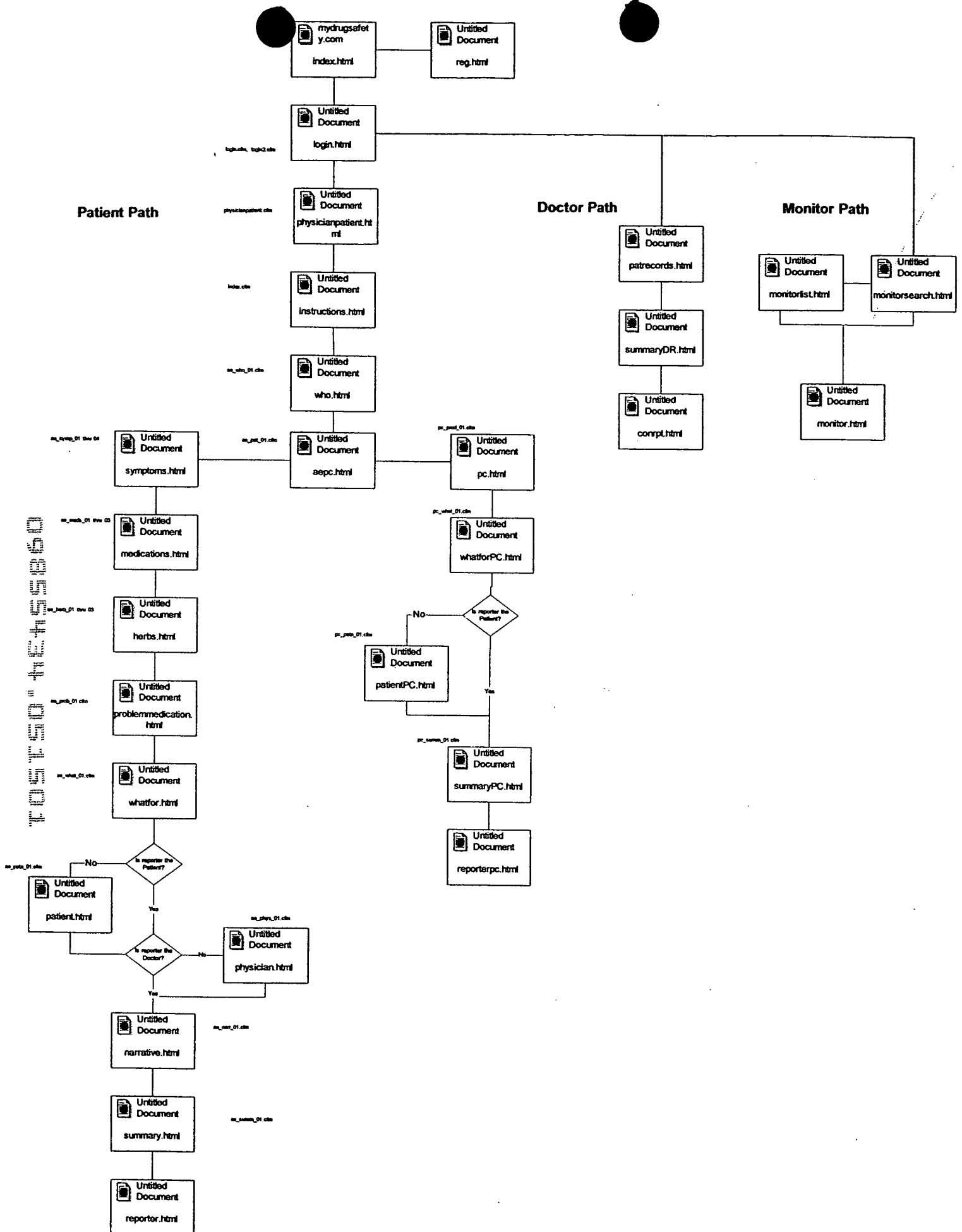
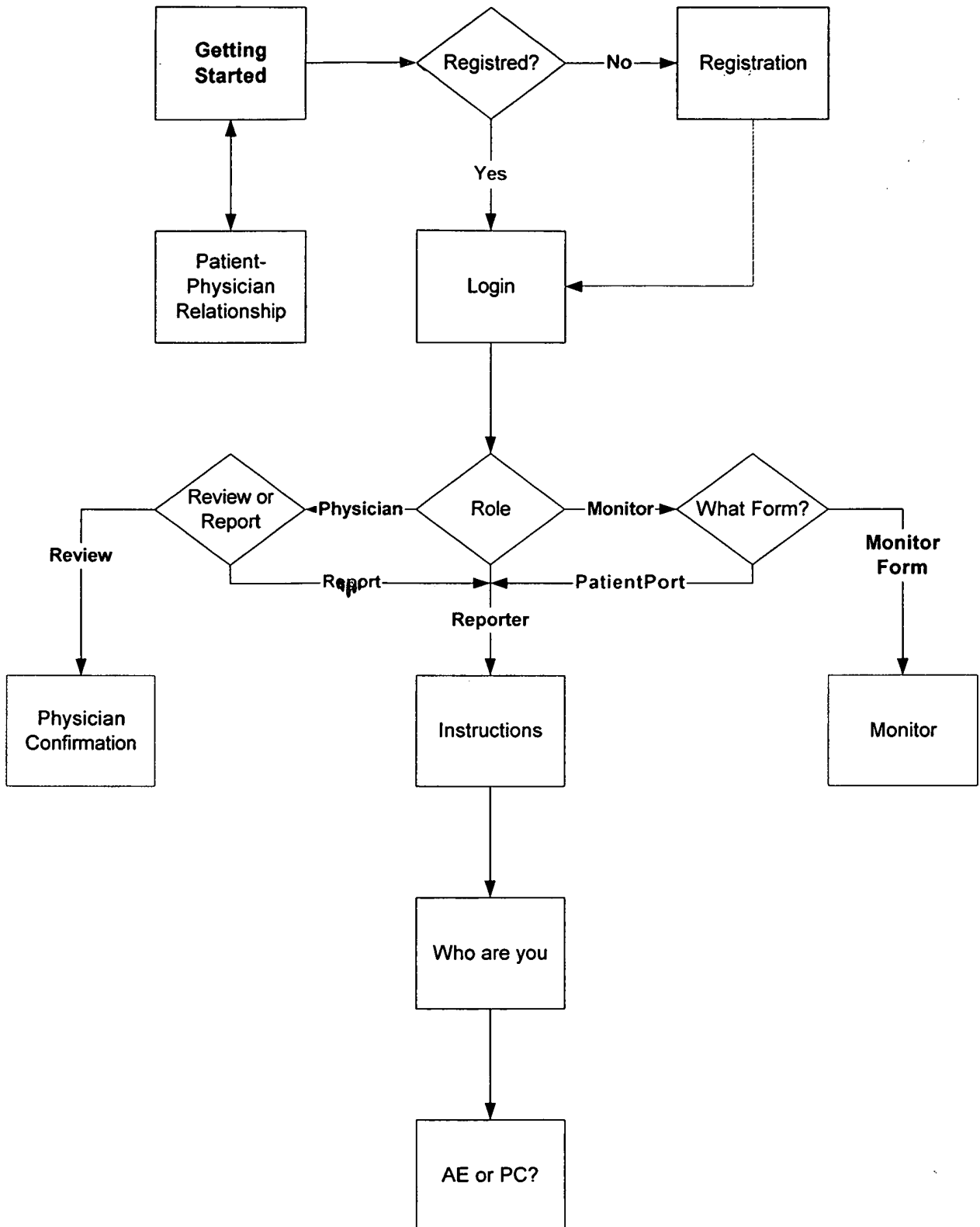


Figure 2



# Portal Pilot Workflow



0955434-051501

# AE or PC Guided Reporting

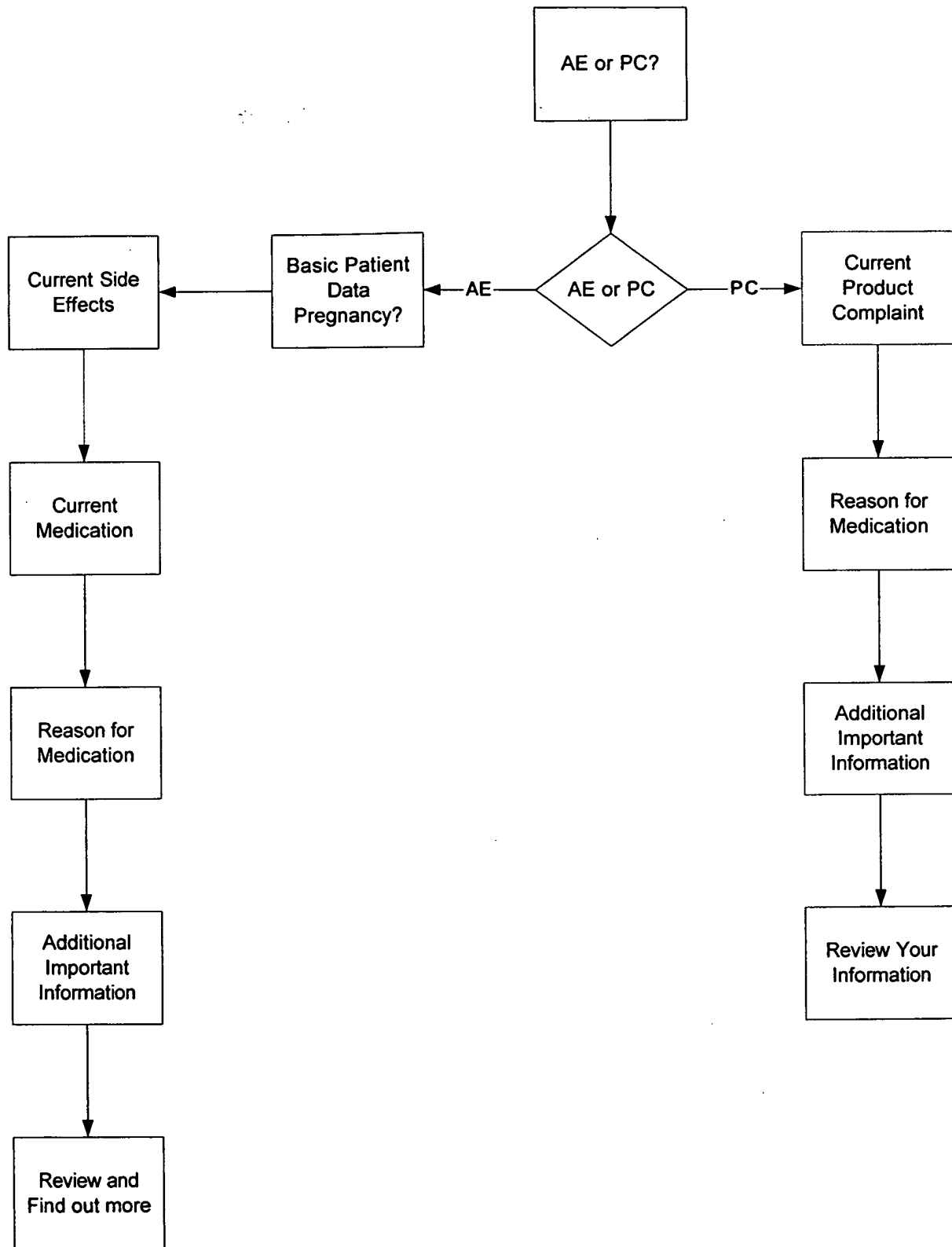
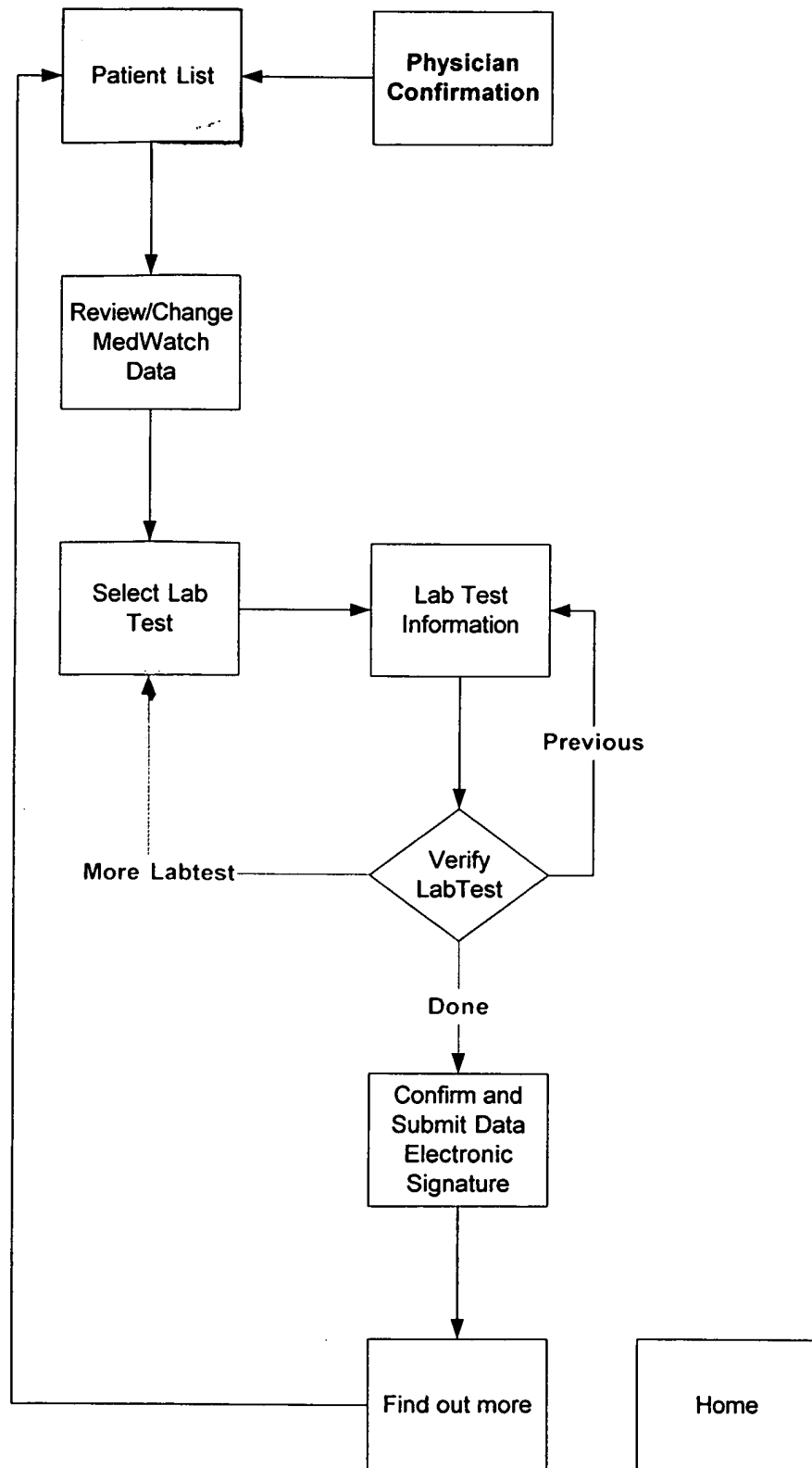


Fig 3b

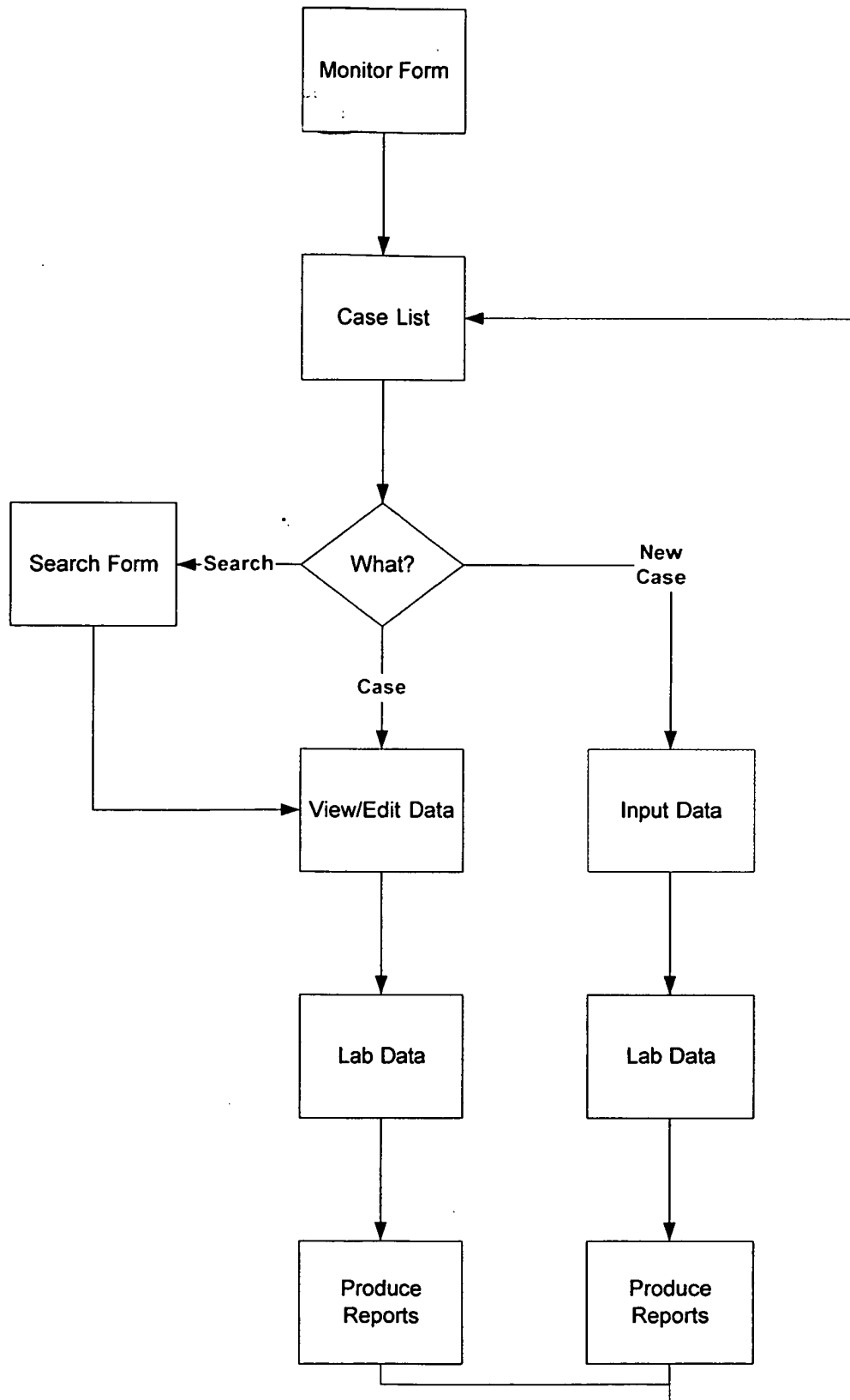
## Physician Confirmation



405150" 4245860

Fig. 3c

# Monitor Form



TEST 50" 4E455860

Home

## Current Side Effects

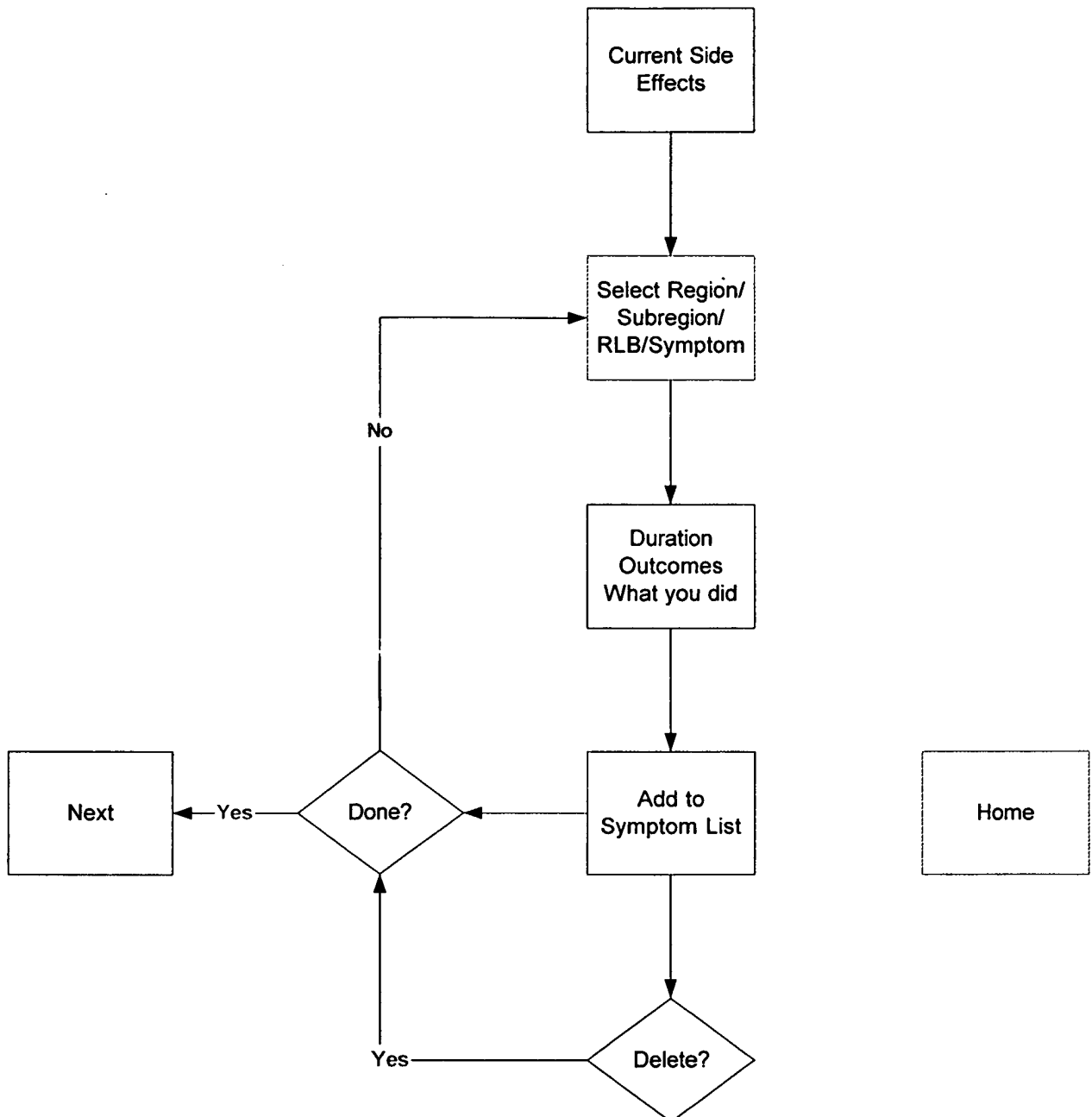
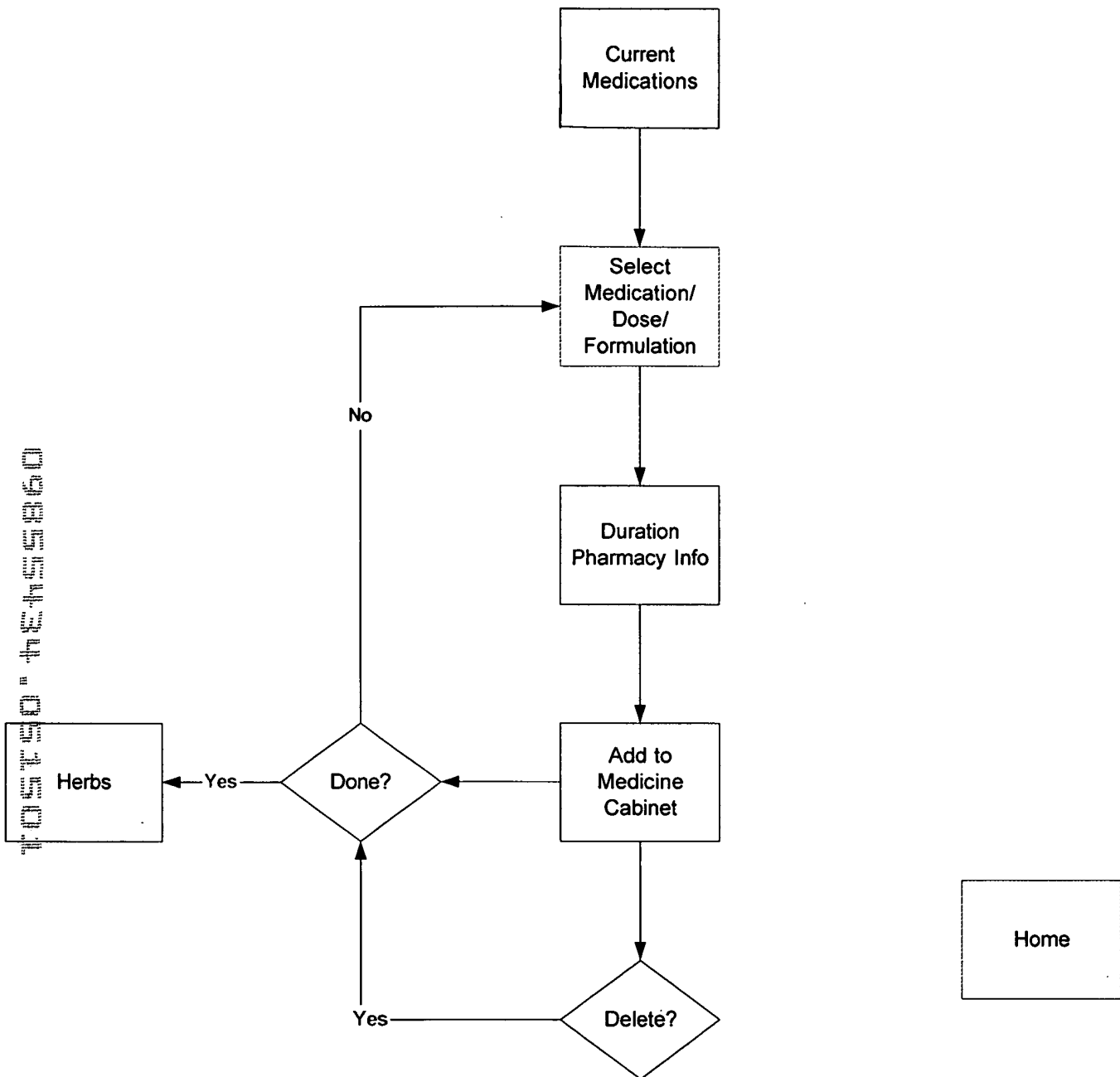


Fig 3e



## Current Medication



## Herbs and Nutritional Supplements

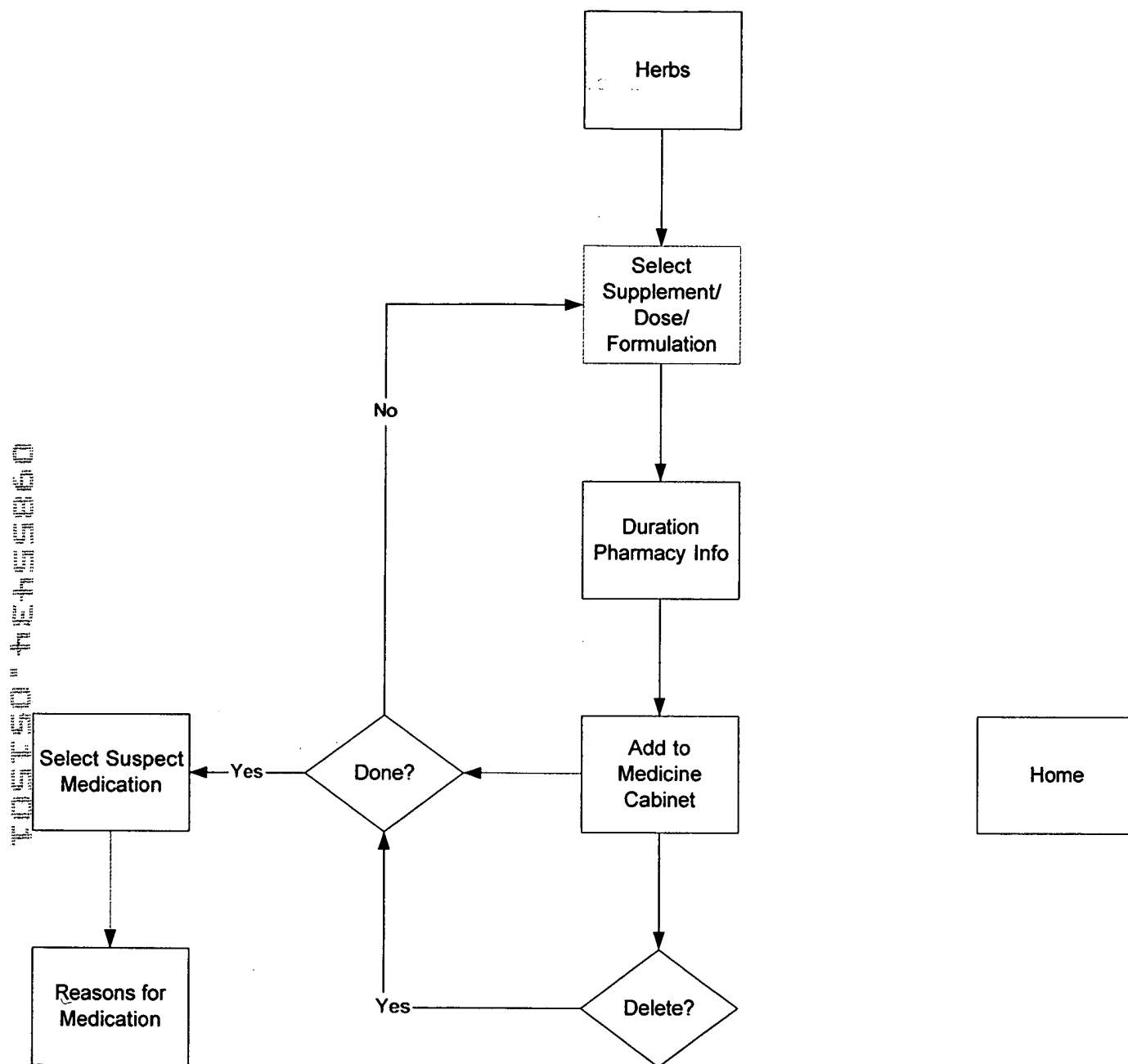
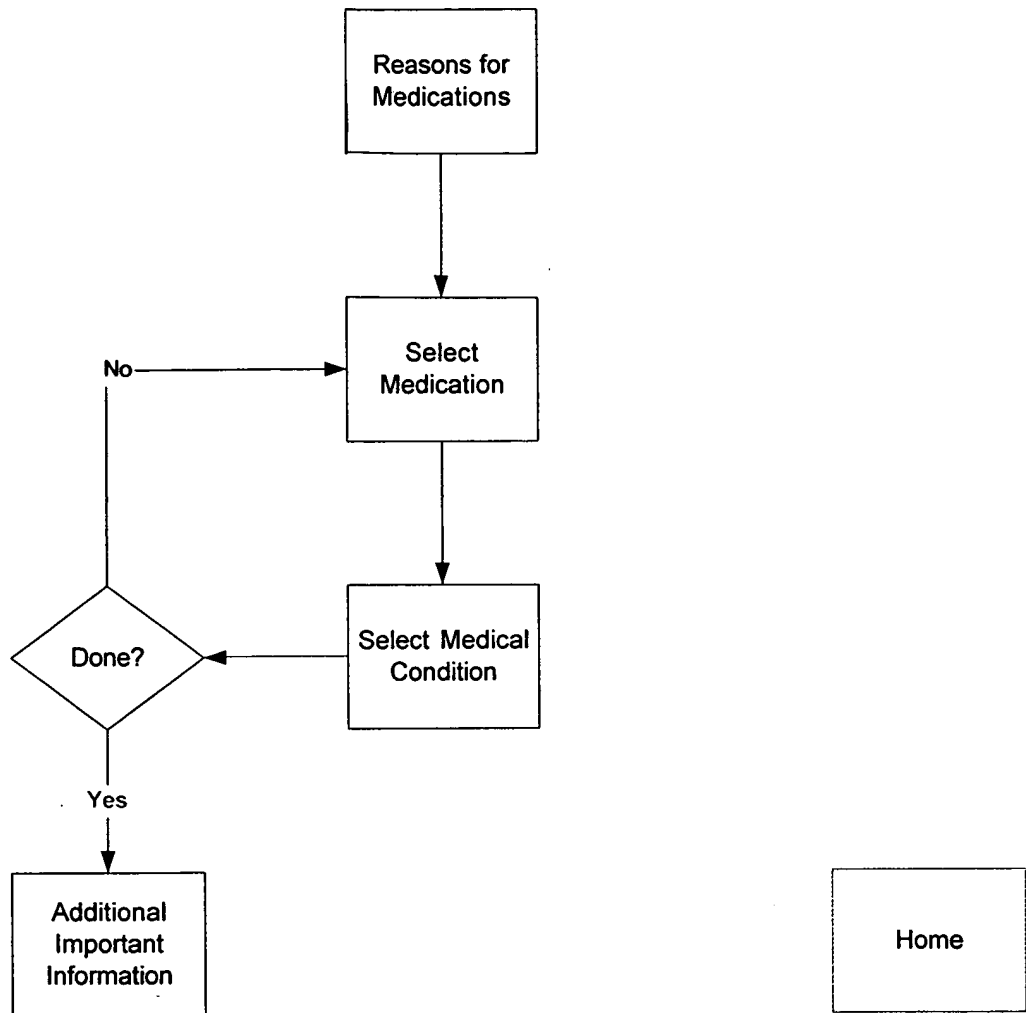
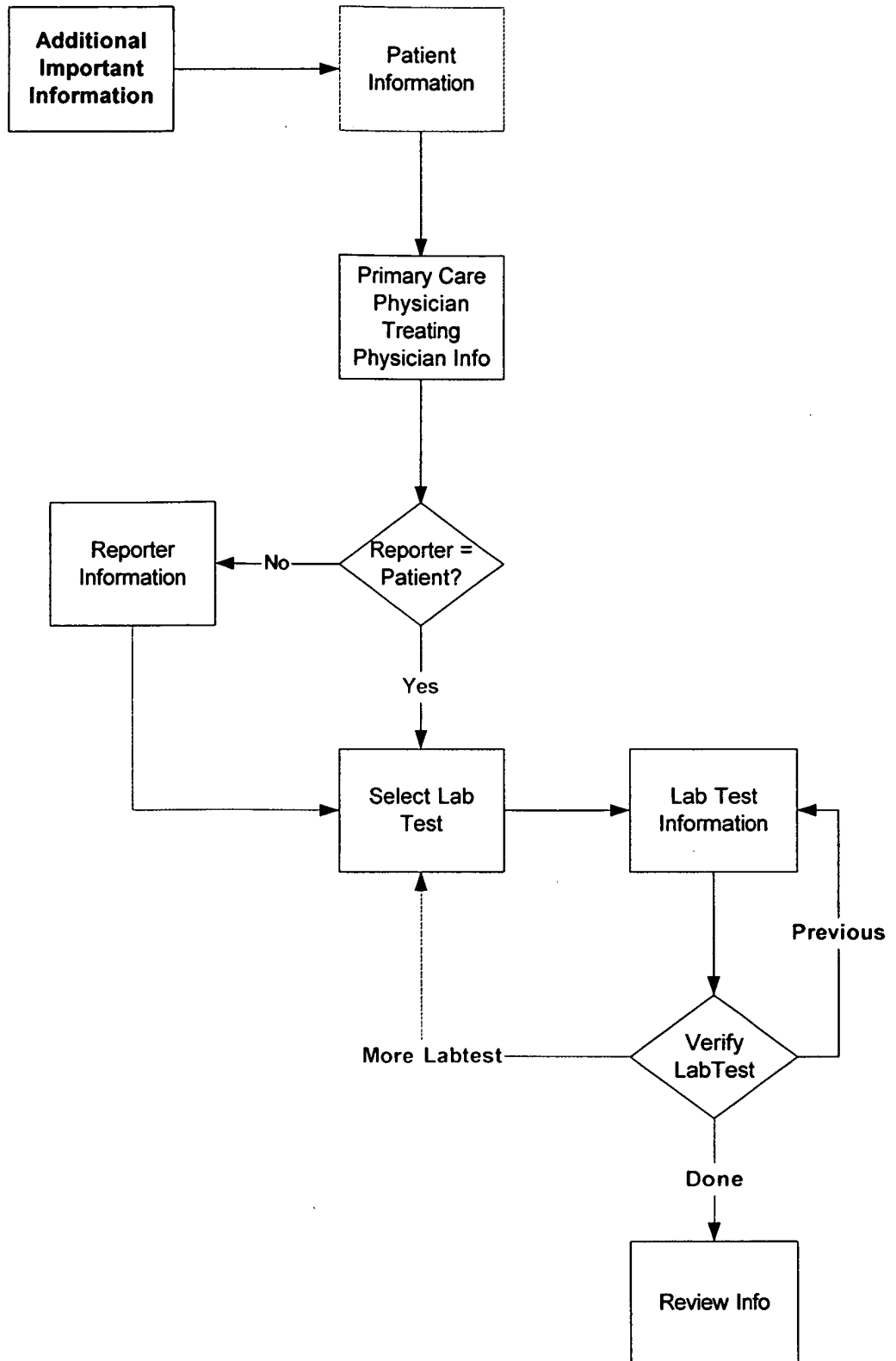


Fig. 39

## Reasons for Medication



## Additional Important Information



Home

**Review Information and Find out More**

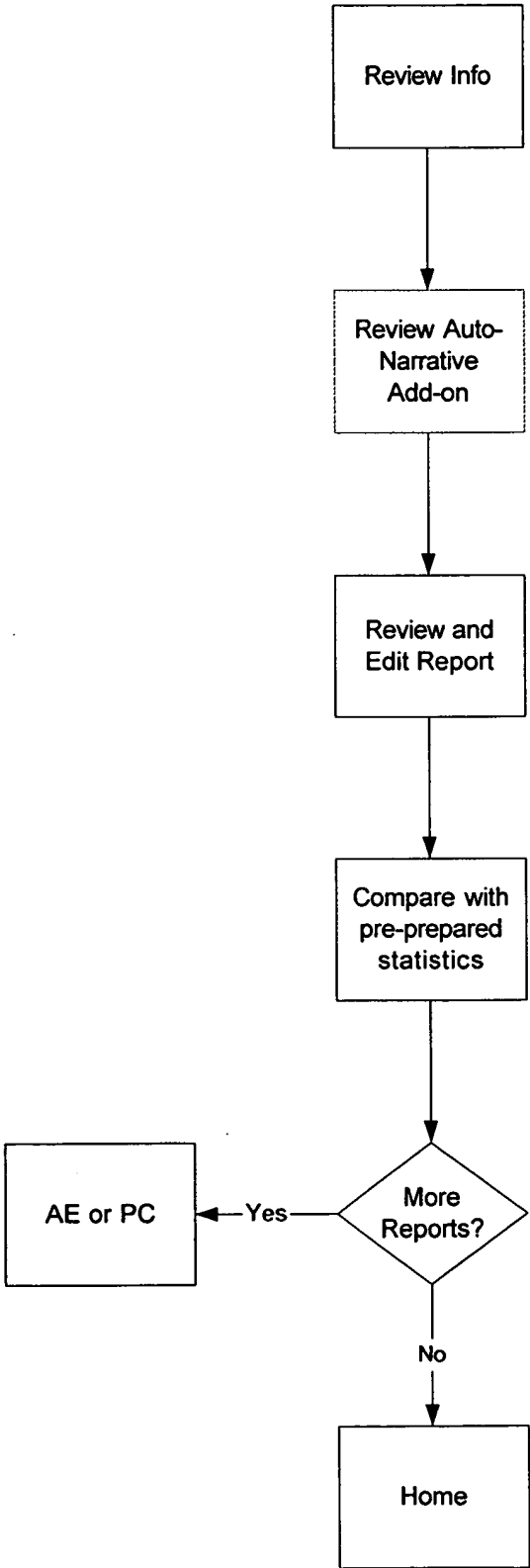


Fig. 30

0955434.051501  
T05T50"4E45860

# Product Complaint

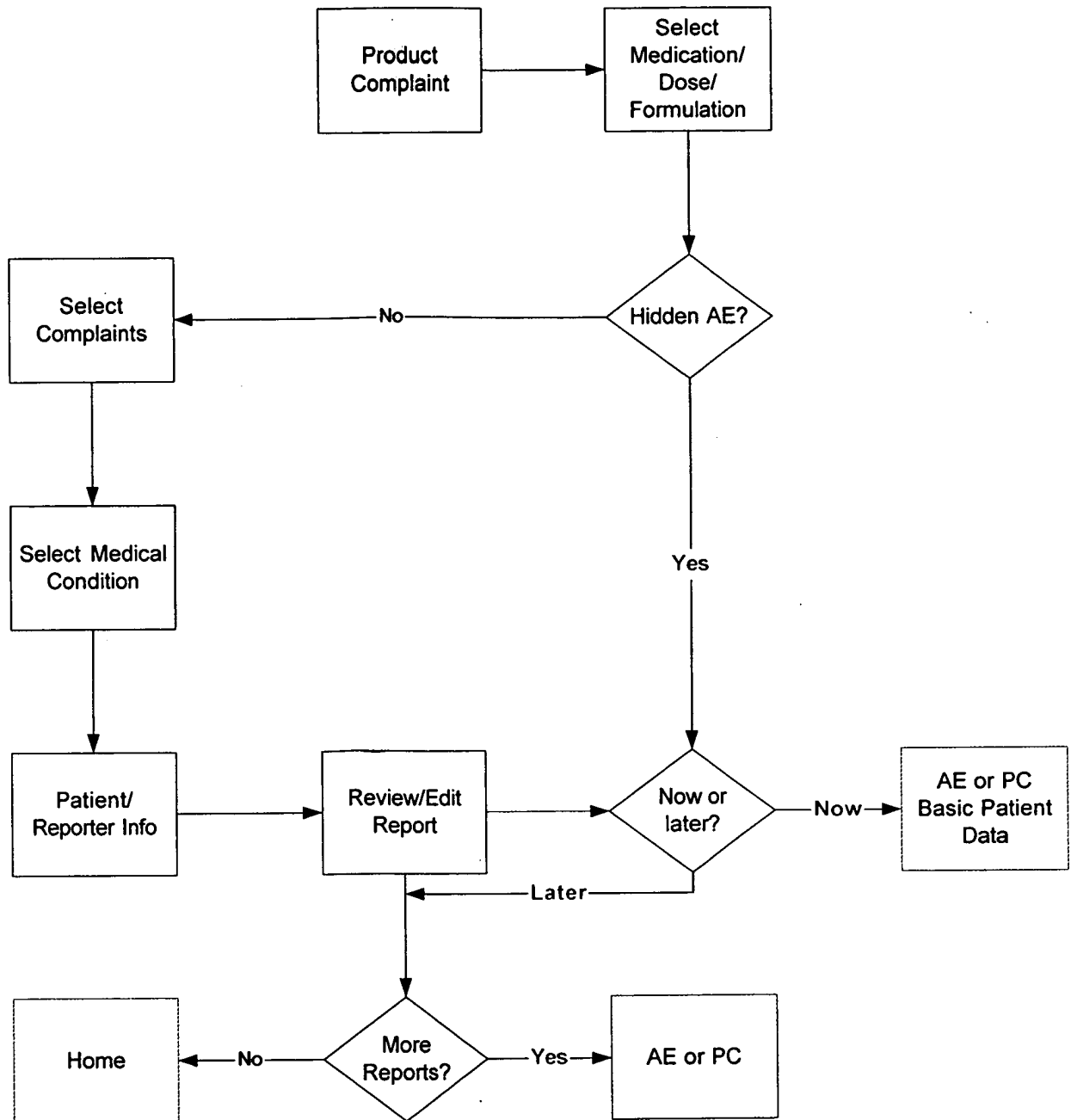


Fig. 3K



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## Registration

### Informed Consent

*In order to complete the report, we may need to contact your physician. Your consent to contact your physician is called informed consent. Only your physician and you will see the information you provide us.*

☐ Accept (required to proceed)

This Web Portal is super-secure. To see your information, define a User-ID and password and log in. Forget your password? We can re-create it: 1) define a secret question (ex: What is my favorite football team) 2) define a secret answer (ex: the SF 49ers). Together these will identify you.

For this pilot, type the 8 digit registration code printed on your trial card.

First Name	<input type="text"/>
Last Name	<input type="text"/>
User ID	<input type="text"/>
Password	<input type="password"/>
Password again	<input type="password"/>
Secret Question	<input type="text"/>
Secret Answer	<input type="text"/>
Phone Number	<input type="text"/>
E-mail	<input type="text"/>

### Getting Started

Login/Registration

Instructions

Who are you

Side Effects and/or  
Product Complaints



## Welcome to MyDrug Safety

### Getting Started

First-time user? [Go to our registration page.](#)

You will need some information about your medication. As preparation, please get all your medication bottles, packets and containers.

Our reporting process contains 5 easy steps. At the end, you will receive a summary report for review.



The symbol provides online help. If you would like to read all the instructions for all the screens [click here to download.](#)

### UserID and Password

UserID

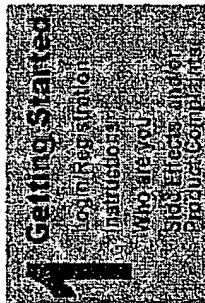
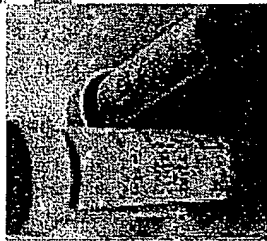
Password

*Change your password?*

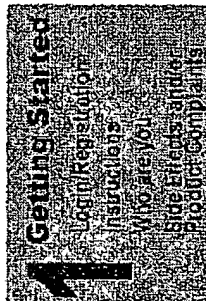
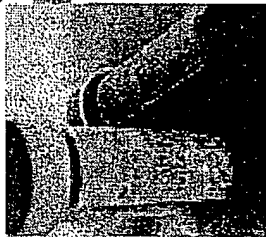
New Password

Repeat Password

[Next](#)







## Patient-Physician Relationship

### The Patient/Physician Relationship

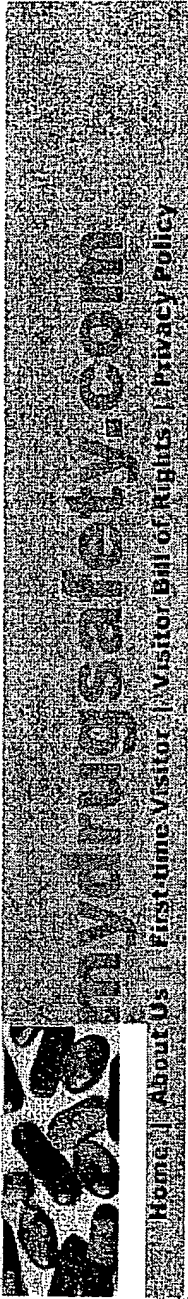


To report your information properly, we have to have your physician confirm it. He will not only help you and us to make drugs safer, he can also help you with your side effect. Please provide us with your and your physician's information so that we can call or write back if we need more information. You can do this at any time by clicking on Registration or you will automatically be asked at the end of the process.

There appears to be an incomplete report in progress from the last time you were logged in. Do you want to recover it?

Clear

Recover



## Instructions

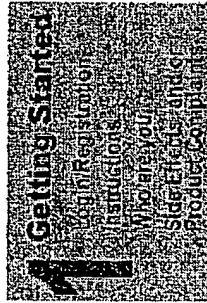
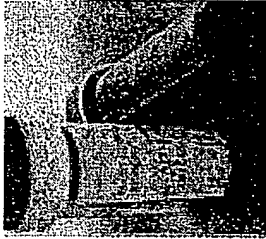
### Easy steps to report a Side Effect or Adverse Event

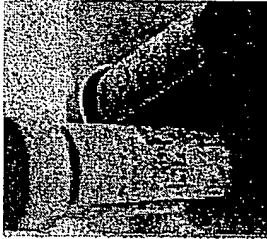
- STEP 1: Side effects or you are experiencing
- STEP 2: Medications you are taking
- STEP 3: Reasons for medication
- STEP 4: Additional important information
- STEP 5: Review your report and find out more

### Easy steps to report a Product Complaint

- STEP 1: Product complaint
- STEP 2: Reason for medication
- STEP 3: Additional important information
- STEP 4: Review your report

Next





**1 Getting Started**  
Login Registration  
Instructions  
Who are you?  
Side Effects and/or  
Product Complaints

## Who Are You?



Who Are You?

Family member/spouse

Patient

Patient Caretaker

Pharmaceutical Representative

Someone else? *Who?*

Treating physician  
---Choose One---



Other Healthcare Professional  
---Choose One---



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**Help**

{helpscreens}



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## Adverse Event or Product Complaint?

### What Do You Want to Report?

☐ AE

Adverse Reaction or a Side Effect you are having

☐ PC

Complaint about your medication

### Family Members Data:

Date of Birth  (mm-dd-yyyy)

or Age

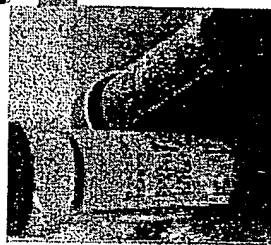
Height   feet  inches  
(ex: 5 feet 2 inches)

Weight  lbs

☐ Male ☐ Female

Pregnant ☒ YES

[Next](#)



**1** **Getting Started**

[Login/Registration](#)  
[Instructions](#)  
[Who are you?](#)  
[Side Effects and/or](#)  
[Product Complaints](#)



## Adverse Event Define a Symptom

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

?

Delete

Done

To delete a symptom from highlight it and press  
Only when you have finished describing all your symptoms press

Click the region where the symptom occurs.:	REGION Which area?:
	Anus
	Bladder
	Buttocks
	Cervix
	Groin
	Labia Minora/Majora
	Ovaries
	Rectum
	Uterus
	Vagina

or

- Getting Started
- Current Side Effects
  - What Symptoms
  - When Started/Ended
  - What Results
  - What to Do
- Current Medications
- Reasons for Medication
- Additional Important Information
- Review Info & Find Out More

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## Adverse Event Define a Symptom

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

?

Delete

Done

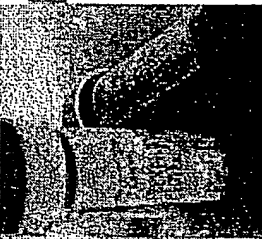
To delete a symptom from highlight it and press

Only when you have finished describing all your symptoms press

Click the region where the symptom occurs.:	REGION Which area?:
	<div> <div>Right-Buttocks</div> <div>Left-Buttocks</div> <div>Both-Buttocks</div> </div>

or

Fig. 106



## Adverse Event Define a Symptom

<p><b>Describe your adverse event.</b> Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.</p>		<p><b>WHAT YOU DID ABOUT IT</b></p> <p><input type="checkbox"/> Did nothing  <input type="checkbox"/> Consulted a Physician  <input type="checkbox"/> Stopped Medication  <input type="checkbox"/> Reduced dose to <input type="text"/>  <input type="checkbox"/> Switched Medication to <input type="text"/>  <input type="checkbox"/> Did it help?  <input type="checkbox"/> Took Medication again and effect came back  <input type="checkbox"/> Took something for it. What? <input type="text"/></p>	
<p><b>SYMPTOM</b> What symptom?</p>		<p><b>DURATION</b></p> <p>When did it start?  <input type="text"/> (mm-dd-yyyy)                  When did it end?  <input type="text"/> (mm-dd-yyyy)                  OR                  How Long did it last?  <input type="text"/> Year <input type="text"/> Month                  Is it still there? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p><b>REGION</b> Which area?:</p>		<p><b>WHAT YOU DID ABOUT IT</b></p>	
<p><b>Click the region where the symptom occurs.:</b></p> <div style="text-align: center;"> </div> <p>or</p>		<p><b>WHAT YOU DID ABOUT IT</b></p>	
<p><b>Buttocks</b></p>		<p><b>WHAT YOU DID ABOUT IT</b></p>	
<p><b>Hip Pain</b></p>		<p><b>WHAT YOU DID ABOUT IT</b></p>	

- 1 Getting Started
- 2 Current Side Effects  
What Symptoms  
What Side Effects  
What Results  
What You Did
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

<b>General Body</b>		<input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Intervention Needed <input type="checkbox"/> Life-Threatening <input type="checkbox"/> Died <input type="text" value="(mm-day-yyyy)"/> Other <input type="checkbox"/>	Did it help? <input type="checkbox"/> YES Did something else <input type="text"/>
<b>Add Symptom to list</b>			

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Help

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Your Medicine Cabinet	
<p>To delete a medication from the list highlight it and press</p> <p><b>Delete</b></p>	<p>When your current medication list is complete press</p> <p><b>Done</b></p>
<p>How long</p> <p>Start <input type="text"/> (mm-dd-yyyy)</p> <p>End <input type="text"/> (mm-dd-yyyy)</p> <p>Still on it <input type="checkbox"/></p> <p>-----Optional info-----</p> <p>Lot # of drug? if present <input type="text"/></p> <p>What Pharmacy did you purchase it at? <input type="text"/></p> <p>Name <input type="text"/></p> <p>Zipcode <input type="text"/></p>	
<p>Medication: Lamisil</p> <p>Dose: 1 %</p> <p>Formulation: CREAM</p> <p>Frequency: 0 Times a day.</p>	<p><b>Add to Medicine Cabinet</b></p>

## 2 Current Side Effects


# Current Medications

# 4 Reasons for Medication

**5 Additional Important Information**

## 6 Review Info & Find Out More


Figure 11



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## What Medication Are You Taking? Suspect Medication

<p>Please select the medication(s) that you think may have caused the event.</p>		
<p>Your Current Medications Are</p> <p><input checked="" type="checkbox"/> Lamisil</p>		
<p><a href="#">Previous</a> <a href="#">Next</a></p>		

- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications  
Medications  
Herbs & Supplements  
Suspect Medication
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

Figure 12

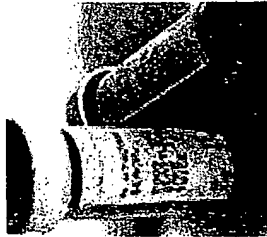


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# What Medication Are You Taking?

## Herbs or Nutritional Supplements



**1** Getting Started

**2** Current Side Effects

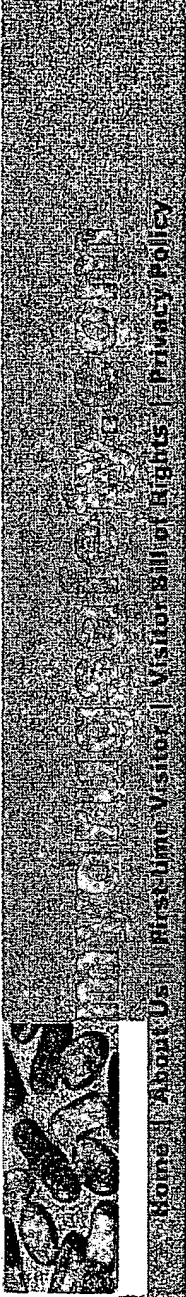
**3** Current Medications  
Medications  
Herbs & Supplements  
Problem Medication

**4** Reasons for Medication

**5** Additional Important Information

**6** Review Info & Find Out More

<p><b>Tell us what herbs or other supplements you are taking.</b></p> <p>Click letter to choose from list.                  A B C D E F G H I J K L M                  N O P Q R S T U V W X Y Z</p>		<p><b>How long</b> <input type="text"/> number of <input type="text"/> days <input type="text"/></p> <p>Start <input type="text"/> mm-dd-yy                  End <input type="text"/> mm-dd-yy  <input type="checkbox"/> Still on it</p> <p>---optional info---                  Lot # of supplement? if present <input type="text"/>                  What Pharmacy did you you purchase it at? <input type="text"/>                  name <input type="text"/> zip code <input type="text"/></p>		<p><b>?</b></p> <p><b>Your Current Herbs</b>                  -----Your Current Medications-----                  &amp;medicine1                  &amp;medicine1</p> <p><b>Add to Medicine Cabinet</b></p> <p>Need To delete a medication from your current list? highlight it and press <b>Delete</b></p> <p>When your current medication list is complete press <b>Done</b></p>	
<p><b>Pick one:</b>                  -----select a medication-----  <input type="text"/></p> <p><b>Not on the list? Enter below</b>  <input type="text"/></p> <p><b>What Dose</b>                  -----select a dose-----  <input type="text"/></p> <p>Times a day <input type="text"/>  <b>What Formulation?</b>                  -----what formulation-----  <input type="text"/></p>					



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## Adverse Event

### What Are You Taking Your Medication For?

What condition are you taking your medication for? Click on your medication and a list of its associated condition/disease will appear. Select the appropriate one. Repeat for each medicine in the list.

Your Medication List			Medical Condition
Medication	Formulation	Dose Frequency (Times a Day)	
Lamisil	CREAM	1 % 4	<div>-----select only one----- Not on the list?...Enter below</div>

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Help

(helpscreens)

Fig. 14

**1** Getting Started

**2** Current Side Effects

**3** Current Medications

**4** Reasons for Medication

**5** Additional Important Information

[Patient Information](#)  
[Physician Information](#)  
[Lab Test Results](#)

**6** Review Info & Find Out More

## Adverse Event Lab Results

Tell us what tests were done  
Click letter to choose from list.


A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Then Select the appropriate test and method for the specimen, enter results. Standard Values for the test will be presented with an indicator for whether the patient values are within range or out of range.

Test	Specimen	Method	Min - Max	Test Value Measurement Time & Date	Status of Test
Albumin	Serum	Colimetry	3.5 - 5.0 g/dl	<input type="text"/> g/dl <input type="text"/> time <input type="text"/> <input type="text"/> dd <input type="text"/> mm <input type="text"/> year <input type="text"/>	<input type="checkbox"/>
				<input type="checkbox"/> multiple test values at this date?	
Aldolase				<input type="text"/> g/dl <input type="text"/> time <input type="text"/> <input type="text"/> dd <input type="text"/> mm <input type="text"/> year <input type="text"/>	<input type="checkbox"/>
				<input type="checkbox"/> multiple test values at this date?	
Aldosterone				<input type="text"/> g/dl <input type="text"/> time <input type="text"/> <input type="text"/> dd <input type="text"/> mm <input type="text"/> year <input type="text"/>	<input type="checkbox"/>
				<input type="checkbox"/> multiple test values at this date?	
Alkaline				<input type="text"/> g/dl <input type="text"/> time <input type="text"/> <input type="text"/> dd <input type="text"/> mm <input type="text"/> year <input type="text"/>	<input type="checkbox"/>
				<input type="checkbox"/> multiple test values at this date?	
Phosphatase				<input type="text"/> g/dl <input type="text"/> time <input type="text"/> <input type="text"/> dd <input type="text"/> mm <input type="text"/> year <input type="text"/>	<input type="checkbox"/>
				<input type="checkbox"/> multiple test values at this date?	

Next

Fig 14A



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## Adverse Event Product Complaint

Check your record

### This Report

A -30Year old pregnant 1 patient, weighing 110 pounds, height 5 feet 6 inches, was taking Lamisil 1 & CREAM 4 Times a day since 07-01-2000, since [how long] [or continuing], for [indication/condition], reportedly experienced an event ['verbatim or reported' term/symptom (R/L/B)] on [date]. This report was received by [pharmaceutical company or GSS] on [date] from [reporter name].

The patient was also taking [prescription medication, over-the-counter or nutraceutical products: concomitant drug 1 (dose, formulation, number of times/day, how long or continuing) for (indication/condition); concomitant drug 2 (dose, formulation, number of times/day, how long

Anything to add?

Blablabla

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1 Getting Started

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3 Current Medications

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5 Additional Important Information

6 Review Info & Find Out More

Review My History

Review Your Info

Other Similar Reports in the FDA



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## Review Your &Who Record Summary Report pat1 patlast

### Review and edit your report,

?

- Getting Started
- Current Side Effects
- Current Medications
- Reasons for Medication
- Additional Important Information
- Review Info & Find Out More  
Review Narrative  
Review your Info  
Check Similar Reports  
to the FDA

Reports complete

Type over text to edit and only when complete press

#### A. Patient Information

Patient Name  
Date of Birth

pat1 patlast

06-16-70

Age at Event

-30

Gender

☐ Male ☐ Female

Pregnant?

☒ Yes ☐ No ☐ Unknown

Weight

110 Lbs

Height

5 feet 6 inches  
(ex: 5 feet 2 inches)

#### B. Adverse Event

Results

☐ Died On (mm-day-yyyy)

☐ Hospitalized Less than 24 Hrs

☐ Hospitalized over 24 Hrs

☒ Disability

☐ Congenital Anomaly

☐ Intervention Needed

☐ Life Threatening

☐ Other

Date of Event

(mm-dd-yyyy)

Date of Report

01-23-2001 (mm-dd-yyyy)

Description

Event Abated?

☐ Yes ☐ No ☐ Unknown

Event Reappeared?

☐ Yes ☐ No ☐ Unknown

C. Suspect Medications

Drug_Name	Dose	Therapy_Dates/Duration	Reason
Lamisil	1 %	From 07-01-2000 to 01-01-2001 Duration:1 Year	Disease 2

D. Concomitant Medication

Drug_Name	Dose	Therapy_Dates/Duration	Reason
-----------	------	------------------------	--------

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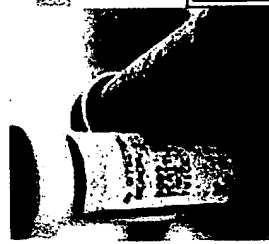
Help

{helpscreens}





# patientPort<sup>SM</sup>



**1 Start**

Login/Registrierung  
Benutzungsanleitung  
Wer sind Sie?  
Arzneimittel-  
Nebenwirkung oder  
Beschwerden über ein  
Arzneimittel

**2 Arzneimittel-  
Nebenwirkung**

Ihre Symptome  
Beginn und Ende  
Direkte Auswirkungen  
Gegensymptome

**3 Ihre  
Medikamente**

Medikamente  
Andere Medikamente  
Heilkräuter & Vitamine

**4 Wechsel  
nehmen Sie?**

<b>Klicken Sie bitte die Region, in der Ihr Symptom sich ausserst</b>	<b>KOPF</b> Wählen Sie die Region?:	<b>SYMPTOM</b> Ihr Symptom	<b>DAUER</b>	<b>WAS UNTERNAHMEN SIE DAGEGEN?</b>
	<b>AUGEN</b>	<b>VERENGTE PUPILLEN</b>	Beginn des Symptoms mm-dd-yy	<input type="checkbox"/> Nichts <input type="checkbox"/> Konsultierte einen Arzt <input type="checkbox"/> Stoppte die Medikamenten-Einnahme Reduzierte die Medikamenten-Dosis auf <input type="checkbox"/> Wechselte das Medikament auf
			Ende des Symptoms mm-dd-yy Wie lange dauerte es? Tage <input checked="" type="checkbox"/> <input type="checkbox"/> Besteht das Symptom immer noch? <input type="checkbox"/> JA	
<b>AUSWIRKUNG DES SYMPTOMS</b> Hat das Symptom direkte medizinische Auswirkungen, wie			Half es? <input type="checkbox"/> JA <input type="checkbox"/> Nahm das Medikament wieder und der Effekt erschien wieder	

Fig. 16a

**5** Zusätzliche  
Informationen  
Galerien-Daten  
Arzte-Daten

FDSP

Hospitalisierung unter 24 Std

☐ Nalm ein Gegenmittel. Was?

SYMPTOM ZUR LISTE HINZUFÜGEN

**6** Bestätigen  
Sie Ihre Daten  
Ihr generierter Bericht  
Alle Ihre Daten  
Vergleichen Sie mit anderen  
Berichten der FDA

Fig. 16a



FOUO 445860

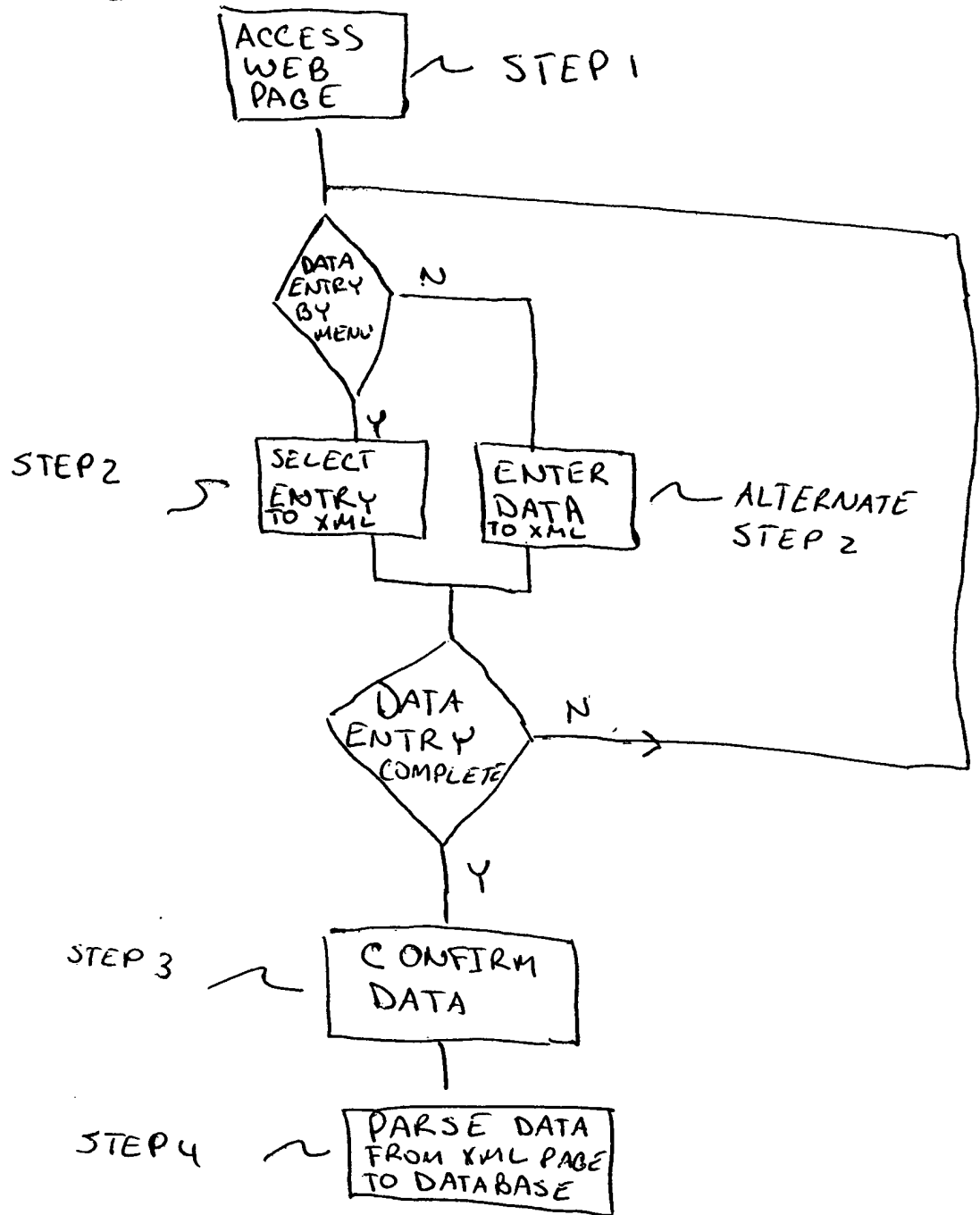


Figure 18